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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,791	08/10/2001	Muhammad A. Sharaf	442211	7448

7590 10/12/2004

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EXAMINER

CHOI, LING SIU

ART UNIT	PAPER NUMBER
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1713

DATE MAILED: 10/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/927,791	SHARAF ET AL.	
	Examiner	Art Unit	
	Ling-Siu Choi	1713	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 and 10-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 8-9 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>09/27/2001</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-2, drawn to a **method** to calibrate a multi-channel fluorescent polynucleotide separation apparatus, classified in class 204, subclass 452.
 - II. Claims 3-6, drawn to a **method** to estimate reference spectral profiles of selected fluorescent dyes using a fluorescent polynucleotide separation apparatus, classified in class 204, subclass 452.
 - III. Claim 7, drawn to a **system** to estimate reference spectral profile of selected fluorescent dyes using a fluorescent polynucleotide separation apparatus, classified in class 204, subclass 603.
 - IV. Claims 8-9, drawn to a **calibration standard** for a fluorescent polynucleotide separation apparatus, classified in class 204, subclass 452.
 - V. Claims 10-13, drawn to a **method** to monitor a separation channel of a fluorescent polynucleotide separation apparatus, classified in class 204, subclass 452.
 - VI. Claims 14-15, drawn to a **composition** for monitoring flow of electrical current through a separation channel of a fluorescent polynucleotide separation apparatus, classified in class 204, subclass 602.

VII. Claims 16-18, drawn to a **method** to calibrate a multi-channel fluorescent polynucleotide separation apparatus having one or more spectral sensors, classified in class 204, subclass 452.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions relates to a **method** to calibrate a multi-channel fluorescent polynucleotide separation apparatus and a **method** to estimate reference spectral profiles of selected fluorescent dyes using a fluorescent polynucleotide separation apparatus.

Inventions II and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practiced by another materially different apparatus such as a signal recorder or by hand.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions relates to a **method** to calibrate a multi-channel

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fluorescent polynucleotide separation apparatus and a **system** to estimate reference spectral profile of selected fluorescent dyes using a fluorescent polynucleotide separation apparatus.

Inventions IV and I, II, III, V, VI, or VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions relates to a **method** to calibrate a multi-channel fluorescent polynucleotide separation apparatus, a **method** to estimate reference spectral profiles of selected fluorescent dyes using a fluorescent polynucleotide separation apparatus, a **system** to estimate reference spectral profile of selected fluorescent dyes using a fluorescent polynucleotide separation apparatus, a **method** to monitor a separation channel of a fluorescent polynucleotide separation apparatus, a **composition** for monitoring flow of electrical current through a separation channel of a fluorescent polynucleotide separation apparatus, and a **method** to calibrate a multi-channel fluorescent polynucleotide separation apparatus having one or more spectral sensors.

Inventions I, II, V, and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions relates to a **method** to calibrate a multi-channel fluorescent polynucleotide separation apparatus, a **method** to estimate reference spectral profiles of selected fluorescent dyes using a fluorescent

polynucleotide separation apparatus, a **method** to monitor a separation channel of a fluorescent polynucleotide separation apparatus, and a **method** to calibrate a multi-channel fluorescent polynucleotide separation apparatus having one or more spectral sensors.

Inventions V, VI, and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions relates to a **method** to monitor a separation channel of a fluorescent polynucleotide separation apparatus, a **composition** for monitoring flow of electrical current through a separation channel of a fluorescent polynucleotide separation apparatus, and a **method** to calibrate a multi-channel fluorescent polynucleotide separation apparatus having one or more spectral sensors.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Mr. Jasbir Singh on august 6, 2004, a provisional election was made with traverse to prosecute the invention of Group IV, claims 8-9. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-7 and 10-18 are withdrawn from further consideration by the

examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

6. **The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith et al. (US 5,747,249).

The present invention relates to a calibration standard for a fluorescent polynucleotide separation apparatus, the standard comprising

	at least four polynucleotides of different length each polynucleotide labeled with a different fluorescent dye having a distinctive spectral profile having a peak
wherein the lengths of the polynucleotides differ from one another such that, upon electrophoretic separation, the peak of the spectral profile of any one of the dyes does not significantly overlap the peak of the spectral profile of any of the other dyes	

(summary of claim 8)

Smith et al. disclose a method to separate and detect tagged polynucleotide, comprising (a) providing a plurality of polynucleotides, each being tagged with a fluorophore, (b) resolving to separate one of the plurality of tagged polynucleotides from other tagged polynucleotides differing by a single nucleotide using an electrophoretic procedure capable of resolving tagged polynucleotides differing by a single nucleotide, and (c) detecting the resolved tagged polynucleotides by means of the fluorophore, wherein the tagged polynucleotides are obtained from one of a set of primer extension reactions in which each of the tagged primer oligonucleotides used in one of the sets is distinguishable by its spectral characteristics from the tagged primer oligonucleotides used in the other sets (claims 1 and 8).

8. Claims 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Ansorge et al. (US 5,912,118).

Ansorge et al. disclose a method to sequence nucleic acids, comprising (a) providing a mixture of labelled nucleic acid fragments of different length with fluorescent


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dyes, (b) separating the labelled nucleic acid fragments according to size by gel electrophoresis, and (c) determining the nucleic acid sequence by means of the labelling of the individual fragments (col. 2, lines 28-40; col. 6, lines 36-40; claims 6, 9, 12).

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ling-Siu Choi whose telephone number is 571-272-1098. The examiner can normally be reached on Monday to Friday.

If attempt to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu, can be reach on 571-272-1114. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


LING-SUI CHOI
PRIMARY EXAMINER

Ling -Siu Choi, Ph.D.

September 27, 2004